DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Carestream Health, Inc.
% Ms. Carolyn Wagner
Senior Manager, Regulatory Affairs & Quality Systems
150 Verona Street
ROCHESTER NY 14608

May 8, 2015

Re: K150342
Trade/Device Name: Touch Ultrasound
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, IYN, ITX
Dated: March 19, 2015
Received: March 24, 2015

Dear Ms. Wagner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150342

Device Name
Touch Ultrasound

Indications for Use *(Describe)*
The system is intended for use by qualified physicians for ultrasound evaluation.
Specific clinical applications and exam types include:
Fetal (including Obstetrics)
Abdominal
Intraoperative
Intraoperative Neuro (also known as Neurosugery)
Pediatric
Small Organ (also known as Small Parts)
Neonatal Cephalic (also known as Neonatal Transcranial)
Adult Cephalic (also known as Adult Transcranial)
Transrectal
Transvaginal
Transurethral
Musculoskeletal (Conventional and Superficial)
Cardiac Adult
Peripheral Vessel (also known as Peripheral Vascular)
Indicated uses are different for different transducers. The Product Data sheet for the system contains a table listing the indicated uses for each transducer that can be used with the system.
The bk3000 ultrasound system is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye. The Cardiac Adult application is not intended for direct use on the heart.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Touch Ultrasound

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
			PW	Tissue	Color	Amplitude	Color	Combined	Other
Specific (Tracks I & III)	B	M	D	Harmonic Imaging	Doppler	Doppler	Velocity Imaging	(Specify 1)	
Ophthalmic									
Fetal 2)	N	N	N	N	N	N		N	
Abdominal	N	N	N	N	N	N		N	
Intra-operative (Specify)	N	N	N	N	N	N		N	
Intra-operative (Neuro) 6)	N	N	N	N	N	N		N	
Laparoscopic									
Pediatric	N	N	N	N	N	N		N	
Small Organ (Specify) 3)	N	N	N	N	N	N		N	
Neonatal Cephalic 4)	N	N	N	N	N	N		N	
Adult Cephalic 4)	N	N	N	N	N	N		N	
Trans-rectal	N	N	N	N	N	N		N	
Trans-vaginal	N	N	N	N	N	N		N	
Trans-urethral	N	N	N	N	N	N		N	
Trans-esoph. (non-Card.)									
Musculo-skeletal (Conventional)	N	N	N	N	N	N		N	
Musculo-skeletal (Superficial)	N	N	N	N	N	N		N	
Intra-luminal									
Other (Specify)									
Cardiac Adult 5)	N	N	N	N	N	N		N	
Cardiac Pediatric									
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vessel	N	N	N	N	N	N		N	
Other (Specify)									

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments:

1) Mode combinations:
   B+M, B+D, B+C, B+D+C. B mode includes Tissue Harmonic Imaging
   (D is PWD, C is Color Flow mapping Doppler including Amplitude(power)Doppler)
2) “Fetal” (including Obstetrics).
3) “Small organ” also known as “Small parts”.
4) “Cephalic” is sometimes called “Trans-cranial”.
5) Not for direct use on the heart.
6) Intra-operative (Neuro) also known as “Neurosurgery”

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Touch Ultrasound_____
Transducer: 9018_____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application									
Specific (Tracks I & III)	B	M	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (Specify)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal 2)	N	N	N	N	N	N		N	
Trans-vaginal 3)	N	N	N	N	N	N		N	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skel. (Conventional)									
Musculo-skel. (Superficial)									
Intra-luminal									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vessel									
Other (Specify)									

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments:____

1) Mode combinations:
   B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler). Tissue Harmonic Imaging.

2) Trans-rectal:
   Prostate.

3) Trans-vaginal:
   Ovaries, Uterus.

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Touch Ultrasound_____
Transducer: 9023_____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks I & III)	B	M	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal 4)	N	N	N	N	N	N		N	
Abdominal 2)	N	N	N	N	N	N		N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric 3)	N	N	N	N	N	N		N	
Small Organ (Specify)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skel. (Conventional)									
Musculo-skel. (Superficial)									
Intra-luminal									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vessel									
Other (Specify)									

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging. Tissue Harmonic Imaging.

Additional Comments:____

1) Mode combinations:
   B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude(power)Doppler)

2) Abdominal:
   Kidney, Liver, Pancreas, Spleen, Lymph Nodes, Gastrointestinal tract, Adrenal glands, Bladder and Aorta:

3) Pediatric:
   Kidney, Liver, Pancreas, Spleen, Lymph Nodes, Gastrointestinal tract, Adrenal glands, Bladder and Aorta

4) Fetal (including obstetrics):
   Gastrointestinal tract, Bladder, Spleen, Head, Liver, Umbilical cord, Kidneys, Vasculature, Aorta, Brain, Limbs, Heart, Adrenal glands, Diaphragm, Facial features, Soft tissue and Spine

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Touch Ultrasound_____
Transducer: 9051_____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application									
Specific (Tracks I & III)	B	M	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal 4)									
Abdominal 2)									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric 2)	N	N	N	N	N	N		N	
Small Organ (Specify 3)	N	N	N	N	N	N		N	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skel. (Conventional) 4)	N	N	N	N	N	N		N	
Musculo-skel. (Superficial) 5)	N	N	N	N	N	N		N	
Intra-luminal									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vessel 6)	N	N	N	N	N	N		N	
Other (Specify)									

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging. Tissue Harmonic Imaging.

Additional Comments:____

1) Mode combinations:
   B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude(power)Doppler)

2) Pediatric:
   hip, spine (except neonatal), renal

3) Small Organs:
   breast, thyroids, testes

4) Musculoskeletal ultrasound (conventional),
   shoulder, hip, spine, knee

5) Musculoskeletal ultrasound (superficial),
   wrist, finger, toes

6) Peripheral vessel
   neck, carotid, vertebra, extremities, venous, arterial

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Touch Ultrasound_____
Transducer: 9062_____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks I & III)	B	M	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify 2)	N	N	N	N	N	N		N	
Intra-operative (Neuro) 3)	N	N	N	N	N	N		N	
Laparoscopic									
Pediatric	N	N	N	N	N	N		N	
Small Organ (Specify)									
Neonatal Cephalic	N	N	N	N	N	N		N	
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skel. (Conventional)									
Musculo-skel. (Superficial)									
Intra-luminal									
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vessel									
Other (Specify)									

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging. Tissue Harmonic Imaging.

Additional Comments:____

1) Mode combinations:
   B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude(power)Doppler)
2) Intraoperative:
   Gall bladder
3) Intra-operative (Neuro) also known as “Neurosurgery”
   Includes spinal cord

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Touch Ultrasound_____
Transducer: 9077_____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks I & III)	B	M	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal									
Abdominal 2)	N	N	N	N	N	N		N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (Specify)									
Neonatal Cephalic									
Adult Cephalic	N	N	N	N	N	N		N	
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skel. (Conventional)									
Musculo-skel. (Superficial)									
Intra-luminal									
Other (Specify)									
Cardiac Adult 3)	N	N	N	N	N	N		N	
Cardiac Pediatric									
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vessel)									
Other (Specify)									

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging. Tissue Harmonic Imaging.

Additional Comments:____

1) Mode combinations:
   B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler,
2) Abdominal:
   Liver, kidney, vessels, spleen etc. and FAST
3) Cardiac Adult:
   Not for direct use on the heart.

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

510(k) Summary:

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

Submitters name: Carestream Health, Inc.

Address: 150 Verona Street, Rochester, NY 14608, USA

Phone: 585-627-6588

Fax: 585-323-7643

Contact person: Carolyn L Wagner, Senior Manager, Regulatory Affairs & Quality Systems

Date prepared: March 14, 2015

Trade name: Touch Ultrasound
Common name: Diagnostic Ultrasound System
Classification names:

Ultrasonic Pulsed Echo Imaging System	(90 IYO, CFR 892.1560)
Ultrasonic Pulsed Doppler Imaging System	(90 IYN, CFR 892.1560)
Diagnostic Ultrasonic Transducer	(90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:

B-K Medical Ultrasound Scanner bk 2300

Device description:

Touch Ultrasound supports the following scanning modes and combinations thereof:
B-mode (incl. Tissue Harmonic Imaging), M-mode, PWD mode, CFM mode, Amplitude (Power) Doppler mode.

The system can perform simple geometric measurements, and perform calculations in the areas of Vascular, Urology, Cardiology and OB/GYN applications.

The system can guide biopsy- and puncture needles.

An optional 3-D module can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.

Transducers
Transducers are linear arrays, convex arrays, and phased arrays.

The patient contact materials are biocompatible.

All transducers used together with bk 2300 are Track 3 transducers.

Acoustic output
The system controlling the Acoustic Output in the Touch Ultrasound is the same as the system in the predicate device Pro Focus 2202. The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta ≤ 720 mW/cm² and MI ≤ 1.9 (Track 3, non ophthalmic).

The Thermal Index values are maximum 6.0, i.e. TI ≤ 6.0

Clinical measurement accuracy
Clinical measurements and calculations are described and accuracies are provided in the User Information.

Thermal, mechanical and electrical safety.
The scanner bk 2300 has been tested by a recognized Certified Body.

Acoustic Output Reporting
The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 9, 2008"

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body.

Comparison of Technological Characteristics: Predicate Device Compared to New Device:

	Predicate Device	New Device
Product Name	bk 2300	Touch Ultrasound
Modes of operation Ref.: [1]	B, M, PWD, CFM [1)] and combinations	B, M, PWD, CFM [1)] and combinations
Intended Use:	Tissue harmonic imaging. Diagnostic ultrasound imaging or image flow analysis of the human body.	Tissue harmonic imaging. Diagnostic ultrasound imaging or image flow analysis of the human body.
Indications for Use:	The system is intended for use by qualified physicians for ultrasound evaluation. Specific clinical applications and exam types include: Fetal (including Obstetrics) Abdominal Intraoperative Intraoperative Neuro (also known as Neurosugery) Pediatric Small Organ (also known as Small Parts) Neonatal Cephalic (also known as Neonatal Transcranial) Adult Cephalic (also known as Adult Transcranial) Transrectal Transvaginal Transurethral Musculoskeletal (Conventional and Superficial) Cardiac Adult Peripheral Vessel (also known as Peripheral Vascular) Indicated uses are different for different transducers. The Product Data sheet for the system contains a table listing the indicated uses for each transducer that can be used with the system. The bk3000 ultrasound system is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye. The Cardiac Adult application is not intended for direct use on the heart.	The system is intended for use by qualified physicians for ultrasound evaluation. Specific clinical applications and exam types include: Fetal (including Obstetrics) Abdominal Intraoperative Intraoperative Neuro (also known as Neurosugery) Pediatric Small Organ (also known as Small Parts) Neonatal Cephalic (also known as Neonatal Transcranial) Adult Cephalic (also known as Adult Transcranial) Transrectal Transvaginal Transurethral Musculoskeletal (Conventional and Superficial) Cardiac Adult Peripheral Vessel (also known as Peripheral Vascular) Indicated uses are different for different transducers. The Product Data sheet for the system contains a table listing the indicated uses for each transducer that can be used with the system. The bk3000 ultrasound system is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye. The Cardiac Adult application is not intended for direct use on the heart.

1) CFM= Color Flow Mapping=Color Doppler and Amplitude (Power) Doppler.

A brief discussion of non-clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence:

The device has been evaluated for acoustic output, thermal, electrical, electromagnetic and mechanical safety, biocompatibility, and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- AIUM/NEMA UD-2, Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-3, Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 60601-1, Medical Electrical Equipment, Part 1: General requirements for safety
- IEC 60601-1-2, General requirements for safety, Collateral Standard, Electromagnetic Compatibility – Requirements and tests
- IEC 60601-2-37, Particular requirements for the safety of ultrasonic diagnostic medical and monitoring equipment
- ISO 14971, Application of Risk Management of Medical Devices
- EN ISO 10993-1, Biocompatibility
- IEC 62304, Medical Device Software – Software lifecycle processes
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

Thermal, electrical, electromagnetic and mechanical safety is unchanged.

Technological characteristics compared to the predicate device
The predicate device has the same technological characteristics as the subject device described above.

Minor differences consist of: Modified trade dress from BK/Analogic to Carestream Health.